II

117TH CONGRESS
2D SESSION

S. 3478

To provide for the designation of biological products as qualified infectious disease products.

IN THE SENATE OF THE UNITED STATES

JANUARY 11 (legislative day, JANUARY 10), 2022

Mr. CASEY (for himself, Mr. CASSIDY, and Mr. MURPHY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To provide for the designation of biological products as qualified infectious disease products.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Generating Antibiotic Incentives Now Through Opening Opportunities to Leverage Science Act of 2022'' or the ''GAIN TOOLS Act of 2022''.

SEC. 2. EXPANDING QUALIFIED INFECTIOUS DISEASE PRODUCTS TO INCLUDE BIOLOGICAL PRODUCTS.

(a) IN GENERAL.—Section 505E of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355f) is amended—

(1) in subsection (c)—

(A) in paragraph (2), by striking ''; or'' and inserting '';'';

(B) in paragraph (3), by striking the period and inserting ''; or''; and

(C) by adding at the end the following:

''(4) an application pursuant to section 351(a) of the Public Health Service Act.'';

(2) in subsection (d)(1), by inserting ''of this Act or section 351(a) of the Public Health Service Act'' after ''section 505(b)''; and

(3) by amending subsection (g) to read as follows:

''(g) QUALIFIED INFECTIOUS DISEASE PRODUCT.—The term 'qualified infectious disease product' means a drug or biological product for human use that—

''(1) is—

''(A) an antibacterial or antifungal drug; or

''(B) a biological product that acts directly on bacteria or fungi or on substances produced by such bacteria or fungi; and

''(2) is intended to treat a serious or life-threatening infection, including such an infection caused by—

''(A) an antibacterial or antifungal resistant pathogen, including novel or emerging infectious pathogens; or

''(B) qualifying pathogens listed by the Secretary under subsection (f).''.

(b) PRIORITY REVIEW.—Section 524A(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360n–1(a)) is amended by inserting ''of this Act, or section 351(a) of the Public Health Service Act, that requires clinical data (other than bioavailability studies) to demonstrate safety or effectiveness'' before the period.

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